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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE DEFENSE EXPERT OPINIONS UNDER FED. R. EVID. 702 BASED ON THEIR USE OF THE CRIMINAL LAW STANDARD OF CERTAINTY (DOC. 7324)

(Assigned to the Honorable David G. Campbell)

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I. INTRODUCTION

Invoking *Daubert*, Plaintiffs have moved to exclude the opinions of Dr. Christopher Morris and Dr. Clement Grassi as irrelevant and confusing because the opinions 1) are based on a "stratospheric" standard that is too high and 2) use a "criminal law standard for causation." Pls. Brief. at 7-11. Plaintiffs – not Drs. Morris or Grassi – have created the issue before the Court. Neither Dr. Morris nor Dr. Grassi included anything in their reports regarding the legal standard that should be applied to medical opinions regarding IVC filters, other than to say, as any expert must, that their opinions were expressed to a reasonable degree of medical certainty. As demonstrated below, the source of the allegedly offending standards comes from Plaintiffs repeatedly pressing these experts in their depositions to assign a numerical value to the level of certainty that they applied to their opinions despite both of them initially testifying that it would be "difficult" to do so. In fact, in both depositions, Plaintiffs – not the experts – initially suggested specific numerical values as a possible level of certainty and invited the experts to agree or disagree.

Using these "standards" of their own creation, Plaintiffs in essence claim the testimony of Drs. Morris and Grassi should be excluded because these experienced medical practitioners are too certain of their opinions. Plaintiffs argue that because Plaintiffs have the burden to prove the elements of the case by a preponderance of the evidence, any medical expert opinions about anything—whether it be the doctors' decades of practical experience with IVC filters or critiques of available literature—will be confusing for the jury if those experts have previously professed more than 51% certainty about those opinions. This argument conflates two distinct concepts: an expert's confidence in his own opinion to meet the standard for admissibility, and the quantum of evidence necessary to meet a legal burden of proof. As an illustration, medical experts commonly testify about their opinions to a "reasonable degree of medical certainty" in both civil and criminal actions. The burden of proof is distinct in each case, but the threshold standard for admissibility and reliability of expert testimony—as to, for

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example, cause of death—does not vary based on the standard of proof. In short, Plaintiffs are wrong as both a legal and practical matter.

Plaintiffs also rely on an incorrect factual premise. Contrary to Plaintiffs' contention that Dr. Morris and Dr. Grassi "based their opinions on the wrong standard," both doctors based their opinions not on any "standard" but on their knowledge, training, and experience, including review of the relevant literature. Both explained this basis in their reports and in their depositions. Nonetheless, Plaintiffs rely on isolated snippets of deposition testimony unmoored from the opinions that Drs. Morris and Grassi actually conveyed. What is clear from the doctors' testimony, however, is that both Dr. Morris and Dr. Grassi treat their expert analysis with the same degree of care, confidence, and reliability that they apply in their everyday professional practice.

Lastly, Plaintiffs selectively quote a brief portion of Dr. Morris's deposition to argue that his opinion that filter fractures rarely become symptomatic is "speculation," and that Dr. Grassi's testimony regarding his experience with Bard filters is "anecdotal." Because the opinions of both experts have a sound basis under *Daubert*, Plaintiffs are wrong on both counts.

For the reasons set forth herein, Plaintiffs' motion should be denied in its entirety.

II. FACTUAL BACKGROUND

A. Plaintiffs—Not the Experts—Insisted on Quantifying Certainty.

Dr. Morris is an interventional radiologist with more than 25 years of experience. Expert Report of Dr. Morris ("Morris Report") Ex. 1 to Pls. Mot., at 1. He has placed more than 800 inferior vena cava filters ("IVC filters") over the course of his career, and his department has retrieved more than 300 Bard retrievable IVC filters alone. *Id.* at 2, 21. Based on his "review of the available literature and [his] personal experience," Dr. Morris's expert opinion is that Bard retrievable IVC filters "are safe and effective." *Id.* at 21. In his report, he stated that he held his opinions "to a reasonable degree of medical certainty." *Id.* at 28.

At Dr. Morris's deposition, counsel for Plaintiffs asked what level of certainty Dr.

Morris applied to his opinions. Deposition of Dr. Morris ("Morris Dep."), Ex 2 to Pls. Mot., at 139:2-3.[1] Dr. Morris responded:

> I don't really know how to answer that question. I think that's more of a legal term, as far as I can tell, but I approached this litigation the same way I practice interventional radiology on a daily basis. I always seek the truth, number one. I use many factors to help render my opinions. That includes first and foremost my personal experience, which I consider large. I also review the medical literature…. I attend national meetings, talk with colleagues, participate in journal clubs, and honestly rely a lot on the FDA to -- to help make these decisions as well . . . . I approach the litigation using the same – same methodology, essentially. So I would say a high level of certainty.

Id. at 139:6-140:4.

Counsel for plaintiffs then pressed Dr. Morris to "put a numerical quantification" to that certainty, and Dr. Morris first said it was a "very difficult question to answer." *Id.* at 140:24-141:5. Dr. Morris then used the contrasting example of his brother (cited by Plaintiffs), to illustrate that in Dr. Morris' own field, he could not be 100% certain due to the limitations of available literature. *Id.* at 141:16-142:14. Plaintiffs' counsel again pressed Dr. Morris for a numerical answer as to how certain he was as to his own opinions, and Dr. Morris stated, "And I can't answer that." *Id.* at 142:18-143:3. Plaintiff's counsel then "suggest[ed]" 80% certain as a starting point. *Id.* at 143:5-9. Dr. Morris responded, "I would say yes, I'm . . . more than a B -- B student, so it would be more than 80 percent, yes. I generally score more than 90 percent." *Id.* 143:18-20.

Later in his deposition, Dr. Morris again emphasized that he reached his opinions in this case in the "same way" he approaches his clinical practice. *Id.* at 183:19-184:6. As to whether IVC filter penetration increases the risk of a fracture, Dr. Morris stated that he had "not decided whether" he "believed that or not," based on "the scientific method." *Id.* at 245:6-20. Plaintiffs' counsel continued "Using the scientific method with the standard of proof of -- of over 80 percent certain? . . . Right? Closer to 90 percent certain,

[1] Any portions of Dr. Grassi's and Dr. Morris's Deposition Transcripts not attached to Plaintiffs' Brief are attached hereto as Exhibit A (Grassi) and Exhibit B (Morris).

right?" *Id.* at 245:21-24. In response, Dr. Morris again clarified:

> Well, that's probably more of a legal term – definition of what certainty is. In medicine we don't talk about numbers as far as our certainty level, so this is a – this is uncharted waters for me, so I guess that might be a broad way to say that, but I'm not a hundred percent sure if I can say that.

Id. at 246:1-6. And upon examination by Defendants' counsel, Dr. Morris returned to this theme, stating that he had difficulty trying to quantify the level of certainty he had about his opinions, and reiterating that he held all of his opinions to a reasonable degree of medical certainty. *Id.* at 343:17-345:1.

Dr. Grassi is an interventional radiologist with more than 30 years of experience with the placement of IVC filters. Report of Dr. Grassi ("Grassi Report"), Ex. 3 to Pls. Mot, at 1. He regularly places and retrieves filters, "several per month." *Id.* at 2. He based all of his expert opinions on "established and fundamental principles of medicine which I (and physicians like me) employ in my clinical practice on a daily basis," and "to a reasonable degree of medical certainty." *Id.* At deposition, Dr. Grassi discussed the available theories and literature regarding why IVC filters fracture, and stated, "I have not yet encountered an explanation which has weight of evidence behind it…. [T]here has not been a mechanism which has yet been proven by the persons who have advanced it." Deposition Transcript of Dr. Grassi ("Grassi Dep."), Ex. 4 to Pls. Mot, at 90:14-91:10. Plaintiffs' counsel then inquired what level of certainty Dr. Grassi would apply in deeming something to be "proven," and Dr. Grassi responded:

> That's a difficult question, only because proof varies scientifically.… I would say that the type of proof that I look for is a convincing explanation where the scientific researcher identifies a problem, can show how and why it occurs, and then can demonstrate a very consistent pattern where the problem can be explained by the exact theory that he or she is proposing.

Id. at 91:11-92:13. Plaintiffs' counsel then asked: "What does convincing mean?" *Id.* at 92:15. Dr. Grassi defined the term as "Where there is really reliable and sound medical evidence behind it." *Id.* at 92:16-17. Plaintiffs' counsel continued, "to what level of certainty would you require for there to be convincing evidence?" *Id.* at 92:18-20. Dr.

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Grassi said, "as I answered before, if one can identify a problem, define what the mechanism is, show a consistent pattern … and provide really reproducible sound examples that show where that has occurred, those would be the factors that as a practicing physician I would look for." *Id.* at 92:21-93:3 (emphasis added). Plaintiffs' counsel then listed several different percentages and other quantitative possibilities for Dr. Grassi, who responded, "Well, I believe I've answered that, but I'll try your question again." *Id.* at 93:6-21 Plaintiffs' counsel repeated: "I gave you various options. Do any of those fit?" *Id.* at 93:23-24. Dr. Grassi responded that because of the grave consequences of a pulmonary embolus, as a practicing physician, he would personally want evidence of filter problems "beyond a reasonable doubt." *Id.* at 94:5-11.

Dr. Grassi also testified regarding available literature discussing whether risk of filter fracture and other complications increased with dwell time. He stated:

> Further investigation still needs to be made for the following reason. We don't know in those papers when the fractures occurred. The methods that were used by those investigators were often to create a point zero or day 1 when the filter was implanted, and then look at a later point in time, or perhaps when the filter was retrieved, and observe that there was a fracture. They observed a trend, but there's no way of knowing when the fracture occurred. . . . So my own opinion is that further work has to be done on this particular subject before I'm convinced of that direct relationship.

Id. at 127:11-128:10. Similarly, Dr. Grassi later acknowledged: "[L]ike many things medically, it's very difficult, and I hesitate to say only or never in medicine." *Id.* at 106:5-7.

B. Opinions on the Limitations of Available Evidence on IVC Filters.

In their expert reports, both Dr. Morris and Dr. Grassi discuss the different types of medical and scientific evidence, and apply those descriptions to studies involving IVC filters. Morris Report at 24. As Dr. Morris explained, Level I studies are "systematic reviews and meta analyses of randomized controlled trials," while Level II studies are "triple blind, prospective, randomized, controlled trials." *Id.* Level III studies are cohort studies, case control, and cross sectional studies, while Levels IV, V, and VI include

lower quality evidence such as case reports and animal studies. *Id.* Dr. Grassi discusses a similar ranking of medical literature by value, observing that while a "randomized, blinded multi-center prospective stud[y]" has the highest scientific or medical value, "[n]o such studies exist with respect to IVC filters." Grassi Report at pp. 4-5; *see also* Grassi Dep. at 80:11-81:4 (discussing varying reliability of different types of studies).

Dr. Morris further testified, "there is a dearth of Level I and Level II evidence in the Interventional Radiology literature, because these studies are very expensive, difficult to conduct, and time intensive to perform." Morris Report at 24. In addition, ethical considerations constrain such research: "A randomized controlled trial … may be unethical … since such studies would be denying one group of patients to an already known life saving therapy." *Id.* at 19; see also Grassi Report at 10 ("Because of the potential serious outcomes of PE, providing a group of patients with no protection against PE would potentially endanger the patients' lives, making such a study untenable. To put these patients at risk purely for investigational purposes would be ethically irresponsible.").

In sum, both Dr. Grassi and Dr. Morris disclose in their reports that the available scientific literature relating to IVC filters has limitations (regardless of outcome), in accordance with how the medical community defines the quality of a study. *See* Grassi Report at p. 8 ("None of the studies reviewed can be classified as randomized, prospective studies, and therefore do not allow us to determine a reliable rate for filter embolization, migration, fracture, tilt, or penetration/perforation for Bard filters, for other IVC filters, comparison of rates among the various filter designs, or allow us to generalize such rates that the nationwide population may experience."). Dr. Morris therefore opines that the conclusions of all available studies "should be interpreted with caution," and that "[t]his skepticism should be applied equally to the many studies showing high and low complication rates with IVCFs." Morris Report at p. 25.

Against this background, Plaintiffs attempt to contort Drs. Morris and Grassi's caution regarding available evidence into a grand legal pronouncement about burdens of

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proof. But neither expert, in testimony or otherwise, has made any statement about a burden of proof, and as experts, they are not required to know or apply such a burden. Instead, they properly relied on and applied their own knowledge, training, and experience, and the resulting opinions are plainly relevant for the jury's consideration.

III. LEGAL ARGUMENT

Pursuant to Federal Rule of Evidence 702, expert testimony is admissible if: "(1) the witness is sufficiently qualified as an expert by knowledge, skill, experience, training, or education; (2) the scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (3) the testimony is based on sufficient facts or data; (4) the testimony is the product of reliable principles and methods; and (5) the expert has reliably applied the relevant principles and methods to the facts of the case." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1043 (9th Cir. 2014).

With two limited exceptions, Plaintiffs do not challenge the reliability of Dr. Morris's and Dr. Grassi's opinions; instead, Plaintiffs argue that their testimony is irrelevant and will confuse the jury. Pls. Brief at 2. According to Plaintiffs, the opinions are irrelevant "because they are based on an incorrect standard of certainty," and "[o]pinions requiring proof beyond a reasonable doubt should be excluded." *Id.* at 6-7. Because Drs. Morris and Grassi's testimony has a "valid connection to the pertinent" issues in the case, *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010), and because neither doctor's opinion "requires" proof "beyond a reasonable doubt" or otherwise, it is relevant and admissible.

A. The Standard of Proof Does Not "Apply to" Expert Opinions.

Plaintiffs argue that "[t]he standard of proof in a civil case is 'more likely than not,' and it applies to expert opinion under the *Daubert* standard." Pls. Brief at 7. Plaintiffs then conclude that expert opinion "based on a different standard" is irrelevant and will confuse the trier of fact. *Id.* Bard concedes the unremarkable proposition that burden of proof in a civil action is a preponderance of the evidence. But as the cases cited in

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Plaintiffs' own brief make clear, the only standards that "apply to" expert opinion are those of Rule 702 and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 589 (1993), and the civil standard of proof does not "apply to expert opinion" at all.

In both *In re Ephedra Prod. Liab. Litig.*, 393 F. Supp. 2d 181, 190 (S.D.N.Y. 2005) and *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1138 (D. Or. 2010), the defendants challenged the reliability of plaintiffs' experts—not relevance, as Plaintiffs do here—arguing that the only scientifically valid way to prove general causation was through controlled epidemiological studies with statistically significant results, and that any testimony short of that scientific certainty was therefore unreliable and inadmissible. Both courts *rejected* that an expert must provide definitive scientific "proof" of causation, so long as the opinion is "reasonably based on good science." *See In re Ephedra*, 393 F. Supp. 2d at 188-89; *McClellan*, 710 F. Supp. 2d at 1112 ("[T]he grounds for the expert's opinion merely have to be good, they do not have to be perfect.") (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). These cases recite exactly what Drs. Morris and Grassi explain in their expert reports: the quality of medical evidence varies widely, and a doctor may choose to consider available, lesser-quality evidence in the absence of a gold standard of proof.

Plaintiffs take this reasoning and stand it on its head, claiming that because a medical expert is *permitted* to express a causation opinion without proving causation to a scientific certainty, that somehow precludes an expert from expressing *greater* than 51% certainty in his own experience. This reasoning is incorrect. An expert may, in accordance with his knowledge, training, and experience, explain his basis for and confidence in his opinion, what types of evidence he and the medical community typically rely upon, and why less robust evidence (such as that available for IVC filters) should be viewed with caution. None of that testimony has any bearing on the burden of proof.

Indeed, multiple courts have held that the burden of proof is for the factfinder, and is not linked to the mandates of *Daubert* and Rule 702:

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> It appears that Plaintiff is implying that if an expert does not use the clear and convincing standard and the presumption of validity, she has based her testimony on incorrect legal standards. Clear and convincing evidence and the presumption of validity are not standards required of expert opinion on invalidity, but standards used by a factfinder. These are legal concepts that are for jury determinations, not for expert witnesses.

Iplearn, LLC v. Blackboard Inc., No. CV 11-876 (RGA), 2014 WL 4967122, at *2 (D. Del. Oct. 2, 2014); *Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996) ("[T]he fact 'that science would require more evidence before conclusively considering the causation question resolved is irrelevant [to the admissibility of expert testimony].'"). Similarly, in *Formax, Inc. v. Alkar-Rapidpak-MP Equip., Inc.*, the court observed that while "[p]resumably many experts are convinced by clear and convincing evidence—or even beyond a reasonable doubt—of their own opinions," the expert witness is "allowed to reach a given conclusion even if unaware of what burden of proof will ultimately be required.… [T]hat burden of proof is not somehow required to be incorporated into the expert's own conclusion prior to giving his testimony." No. 11-C-298, 2014 WL 3057116, at *2 (E.D. Wis. July 7, 2014) (emphasis added).

In other words, so long as Dr. Morris and Dr. Grassi's opinions are methodologically sound, their professed level of confidence has no bearing on the admissibility of their testimony. "Reliability does not depend on whether the burden of proof is 'preponderance of the evidence,' 'clear and convincing,' or 'beyond a reasonable doubt.'" *Iplearn, LLC*, 2014 WL 4967122, at *2; *see also Primiano*, 598 F.3d at 564 ("The test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology."); *Noblesville Casting Div. of TRW, Inc. v. Prince*, 438 N.E.2d 722, 729 (Ind. 1982) ("[R]easonable certainty" is primarily a formulation designed to guarantee the trustworthiness or reliability of the opinion offered, rather than the fact to be proved.").

In sum, an expert need not know the burden of proof nor apply it to his own testimony. Dr. Grassi's and Dr. Morris's opinions do not "require" proof of causation either "beyond a reasonable doubt" or by "conclusive evidence of absolute certainty." *Cf.*

Pls. Brief at 7. Neither expert has offered any legal opinion of what a plaintiff must prove. Instead, in response to repeated demands that they quantify the unquantifiable, these physicians described the level of confidence and comfort *in their own opinions*, consistent with their everyday professional practices. *See* Morris Dep. at 139:6-140:4 ("I think that's more of a legal term, but I approached this litigation the same way I practice interventional radiology on a daily basis"); Grassi Dep. at 92:21-93:3 (describing the "factors that as a practicing physician I would look for" in assessing scientific evidence). Accordingly, the Court should reject Plaintiffs' attempts to impose any standard governing the admission of expert testimony other than that set forth in Rule 702 and Daubert case law.

B. Drs. Morris and Grassi's Opinions are Relevant and Admissible.

Plaintiffs declare that because Dr. Morris and Dr. Grassi express high confidence in their own opinions, the opinions are "not relevant in a civil case." Plaintiffs offer no analysis to support this pronouncement, instead simply citing the general proposition that medical professionals can and do consider data beyond "randomized clinical trials or . . . statistically significant evidence." Pls. Brief at 8-9. Neither Dr. Morris nor Dr. Grassi disputed that principle in their opinions: indeed, Dr. Morris acknowledged that he had to operate on *less than* 100 percent certainty because no Level I or Level II evidence exists for IVC filters. Morris Dep. at 141:16-142:14. Nor did either expert suggest that the Court should impose any standard—"stratospheric" or otherwise—on admissibility of expert evidence. Plaintiffs are attacking a straw man. By admitting Dr. Morris's and Dr. Grassi's testimony, the Court is not somehow declaring any other testimony inadmissible.

Still, Plaintiffs argue that Dr. Morris's and Dr. Grassi's opinions will not "assist the trier of fact." Pls. Brief at 9; *cf.* Fed. R. Evid. 702(a) (permitting testimony if "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue."). Contrary to Plaintiffs' description of the testimony, neither Dr. Morris nor Dr. Grassi "insisted" on any level of certainty across the board, or indicated that they planned to unilaterally express any

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"required" percentage of confidence to the jury. Instead, both experts resisted any attempt to quantify their own level of confidence in their opinions, describing both their methodology and evaluation of evidence in practice, and discussing both the limitations and importance of less than Level I or Level II evidence, including *both* evidence relied upon by Plaintiffs' experts and contrary evidence referenced by Drs. Morris and Grassi. *See In re Epehdra*, 393 F. Supp. 2d at 194 ("[T]he gaps between such data [generally relied upon by physicians when conclusive proof is unavailable] and definitive evidence of causality are real and subject to challenge before the jury."). Dr. Morris's and Dr. Grassi's opinions, including their opinions about the safety and efficacy of Bard IVC filters and the limitations of contrary evidence—clearly have a valid connection to the inquiry in this matter, and are therefore relevant. *See id.* at 198 (observing that plaintiff's expert could be cross-examined and that jury may accept competing expert testimony that there was no scientific basis for concluding that ephedra causes seizures).

Plaintiffs cite no authority for the proposition that an expert's confidence in his own opinion will somehow lead the jury to confuse the burden of proof.[2] *See generally Ambrosini, 101 F.3d at 135.* ("The dispositive question is whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue,' not whether the testimony satisfies the plaintiff's burden on the ultimate issue at trial.") (emphasis added). The jury will not be confused, and the Court should not restrict evidence useful to the jury simply because Drs. Morris and Grassi have expressed confidence in their own opinions.

C. The Opinions Are Neither Speculative Nor Unreliable.

In addition to their unsupported assertions about the purported "criminal law standard," Plaintiffs also argue that certain opinions of Dr. Morris and Dr. Grassi are "based on speculation or unreliable anecdotal experience." Pl. Brief at 6. Specifically,

[2] The sole case Plaintiffs cite held that it was unconstitutional for Arizona to *require* a criminal defendant to prove mental retardation with "a degree of certainty." *Smith v. Ryan*, 813 F.3d 1175, 1198-99 (9th Cir. 2016).

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Plaintiffs argue that Dr. Morris's opinion regarding asymptomatic limb fractures was "speculation" and that Dr. Grassi's opinion regarding his own practice experience with Bard filter devices is "anecdotal and not based on sufficient data." Pl. Brief at 11-12. This Court should reject both arguments.

1. <u>Dr. Morris Said That Plaintiffs' Hypothetical Was "Speculative," Not His Own Testimony</u>.

In his report, Dr. Morris states "Although most limb fractures remain asymptomatic, they have been associated with embolization to the heart and pulmonary arteries." Morris Rep. at 25. Plaintiffs contend that Dr. Morris in his deposition admitted that his opinion that most filter fractures were asymptomatic was "speculation." Plaintiffs take Dr. Morris's testimony wholly out of context. At deposition, Dr. Morris and Plaintiffs' counsel engaged in an extended colloquy about Dr. Morris's experience and clinical judgment—supported by relevant literature—that a filter fracture can be and often is asymptomatic. Morris Rep. at 25; Morris Dep. at 208:23-209:6.[3] Plaintiffs' counsel asked Dr. Morris if an asymptomatic fracture could migrate in the direction of the heart. Dr. Morris acknowledged that such a case "would be rare, but that could happen," *Id.* at 203:5-13, and that if such migration *did* occur, "[r]arely it can perforate the wall of the heart and cause" tamponade or an infection: "Those are extremely rare events, but that could potentially happen." *Id.* at 206:20-207:8; *see also id.* at 209:7-12.

Plaintiffs' counsel then raised the hypothetical of a death without an autopsy, arguing: "you don't know as you sit here today whether that's happening all over the place every day or every week in this country and it's not being recognized but filter fractures are killing people and they're dying at home and nobody's connecting it to the filter?" *Id.* at 209:19-22:6. Dr. Morris pointed out that counsel was asking him to prove a negative: "how can I prove a negative if there's no evidence on a negative?" *Id.* at 212:13-15. At this point, the following exchange occurred:

[3] Dr. Grassi offered this same opinion in his own report. *See* Grassi Report at 4 ("In case of filter fracture, migration, tilt, and perforation, a large percentage of patients who experience such events are typically asymptomatic.").

> **Q:** You can just answer my question, which was, You don't know as you sit here today whether this is happening frequently and not being detected?
> **A:** I don't know that - -
> **Q:** Right?
> **A:** I don't know that it is; I don't know that it isn't.
> **Q:** Right. And so you cannot say to a reasonable degree of scientific certainty that this event is rare unless you know the answer to the question of whether it's recognized when it happens on a regular basis, right?
> **A:** It's speculation.
> **Q:** You don't know if [death following asymptomatic fracture] is rare or not, do you?
> **A:** I – that's really difficult to answer because we know from some of these observational studies that have filter fragments in their chest, the vast majority of them are asymptomatic and they're not reporting large numbers of deaths in their patient population, so…

Id. at 212:16-212:14 (objections omitted).

Dr. Morris's testimony clearly does not admit that *his opinion* that "most limb fractures remain asymptomatic" is speculation. Instead, his testimony states that it would be "speculation" to state that fatal yet asymptomatic fractures occurred frequently, *because there is no evidence to support that it is happening*. *See id.* at 212:11-213:14. Dr. Morris's opinion, meanwhile, is based on both his extensive knowledge, training, and experience as an interventional radiologist who has placed and retrieved hundreds filters, and the relevant scientific literature. *See id.* at 230:24-231:7 ("I'm still looking for a proven case of a filter fragment embolization that's caused a death. Maybe there is. Maybe you know of one, but I haven't -- I haven't seen that in the literature or a case report of that."); *id.* at 231:18-232:22 ("[S]ome of these observational studies have shown fracture fragments in -- in numbers of their patients, and they have generally been asymptomatic, according to the papers."); *id.* at 342:15-343:16 ("[W]e've placed roughly 1,000 Bard retrievable filters over the years and we've removed … over 300 of those filters, and we've only encountered four fractures of a Bard filter. We've seen other fractures of some of the other filters we've placed. And I only know of two cases where there was -- where there -- where there were fragments in the chest, one in the right ventricle and another in the -- several fragments in the pulmonary arteries.").

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Plaintiffs' charge that Dr. Morris's opinion regarding asymptomatic filter limb fractures is "speculation" is unsupported by his testimony, and the Court should deny this portion of Plaintiffs' motion to exclude.

2. Dr. Grassi's Clinical Judgment, Based on His Decades of Practice, is Reliable.

Plaintiffs dismiss Dr. Grassi's description of his own ample experience with implanting and retrieving Bard filters as "anecdotal." Dr. Grassi has regularly placed filters throughout his more than 30 years in practice, and continues to implant and retrieve several IVC filters every month. Grassi Report at 2. Over the years, he has implanted well over 100 Bard retrievable filters, and has retrieved 24 or more of the same. Grassi Dep. at 51:21-63:9 (discussing implanting 10-12 G2 or G2X filters, more than 50 Eclipse filters, around 20 Meridian filters, and 50 or more Denali filters, and retrieving at least four G2 filters, at least 8 Eclipse filters, at least 6 Meridian filters, and 6 Denali filters). He has never had a patient with a complication from an Eclipse, Meridian, or Denali filter, *Id.* at 61:3-63:9, and cannot recall any fractures in G2/G2x filters. *Id.* at 53:8-15. He has seen one perforation with a G2 filter in his own patient, *Id.* at 56:8-17, and between the scientific meetings he has attended, his extensive practice experience, and the experience of his colleagues, he is aware of five or six total Recovery perforations, and only one or two Recovery fractures. *Id.* at 53:15-56:17. Consistent with this data, his relevant opinion states: "In my own experience, I have not encountered unexpectedly high complication rates with the Bard filter devices." Grassi Report at 12.

An expert "certainly may rely on his own clinical experience in stating his opinion." *McClellan*, 710 F. Supp. 2d at 1138. This is because medical professionals commonly and properly rely on "their knowledge and clinical experience combined with review of the relevant medical literature," just as Dr. Grassi did here. *Id.* at 1116; *see also* Fed. R. Evid. 703 (permitting expert opinion to be based on the "kinds of facts or data" reasonably relied upon by "experts in the particular field"). For instance, in *Lewert v. Boiron, Inc.*, 212 F. Supp. 3d 917, 934 (C.D. Cal. 2016), the court rejected plaintiff's

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attempt to exclude purportedly anecdotal evidence from physicians as unreliable, observing that expert also testified that the medical community relied upon clinical experience and anecdotal evidence in treating patients. Plaintiffs are free to cross-examine Dr. Grassi regarding the limitations of his own experience, but it is not "unreliable as a matter of law." *See id.* The Court should reject this portion of Plaintiffs' Motion as well.

IV. CONCLUSION

For these reasons, Defendants request that this Court deny Plaintiffs' Motion.

RESPECTFULLY SUBMITTED this 27th day of September, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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